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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,476	01/24/2000	David Whitaker	P0435OUSO-PHI-1196	7190

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/13/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 09/490,476	Applicant(s) WHITAKER, DAVID	
	Examiner Ashwin Mehta	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7 and 20 is/are allowed.
- 6) ☒ Claim(s) 6, 8-19, 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification for containing blank lines in place of ATCC accession numbers on page 7 is withdrawn, in light of the insertion of the accession numbers.
3. The objection to claims 1, 5, and 7 is withdrawn in light of the claim amendments.
4. The rejection of claims 1-32 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the claim amendments.
5. The rejection of claims 1-32 under 35 U.S.C. 102(e)/103(a) is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

6. Claims 6, 8, 11, 15, 19, 21, 28, and 32 remain and new claims 33, 34, and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 29 July 2002 under item 7. Applicant

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traverses the rejection in the paper received 29 October 2002. Applicant's arguments were fully considered but were not found persuasive for claims 11, 15, 19, 24, 28, and 32.

Regarding the indefinite issue concerning the relative terms in claims 11, 15, 19, 24, 28, and 32: Applicant argues that each of the claims recites two requirements: that 34G13 be an ancestor of the plant, and that the claimed plant be "capable of expressing a combination of at least two 34G13 traits" selected from a Markush grouping (response, paragraph bridging pages 10-11). However, this issue was not raised in this rejection. Applicant also argues that the terminology of the adjectives is well known in the art and would be understood by one skilled in the art. Applicant argues that the terminology of the adjectives is not unduly narrative or imprecise as they characterize and positively recite the degree of expression of the particular traits within Tables 1-4 (response, paragraph bridging pages 10-11). However, the specification does not teach that the traits in Tables 1-4 can be described in the manner in the claims. The specification does not define the separation from outstanding grain yield, for example, from good grain yield.

Applicant argues that the claims now indicate that the plants have 50% of the alleles of 34G13, and that the plants be able to express a combination of two traits of 34G13 (response, paragraph bridging pages 10-11). However, the recitation of "50% of its alleles" does not affect the issue raised in this rejection. That the claimed plants are to express a combination of two traits that are also expressed by 34G13 also does not overcome the rejection, as it is not clear what separates a plant having, for example, excellent stalk strength from good stalk strength. Applicant also argues that it is against the policy of the patent statutes to bar patent protection for inventions that are incapable of precise definition and assert that the terms in the claims are as

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precise as the subject matter of the invention permits (response, page 11, 1st full paragraph).

However, it is not clear, for example, what defines a plant as having very good stay green from outstanding stay green.

In claim 6: there is improper antecedent basis for “protoplasts” in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 5.

In claims 8 and 21: the recitation “manipulated to be male sterile” renders the claims indefinite. It is not clear if the claims are directed towards detasseled plants, or plants that have been transformed with a transgene conferring male sterility. The following amendments are suggested: 1) in claims 8 and 21, replace “manipulated to be male sterile” with --detasseled--; 2) add a new claim 41 directed towards a method of producing a transgenic male sterile maize plant comprising transforming the maize plant of claim 2 or 20 with a transgene that confers male sterility, and a new claim 42 directed towards a transgenic male sterile maize plant produced by the method of claim 41.

In claims 11, 15, 19, 24, 28, 32, 38, and 39: the recitations “has derived at least 50% of its alleles” in claims 11, 15, 19, 24, 28, and 32, and “deriving at least 50% of its alleles” in claims 38 and 39 render the claims indefinite. It is not clear what is meant by “derived” and “deriving.” Have the alleles been transformed into the claimed plants, did the claimed plants inherit the alleles in crosses, etc.?

In claim 33: the recitation “a hybrid maize plant” in line 4 renders the claim indefinite. The claim does not clearly indicate that the hybrid maize plant in the recitation is the same as 34G13, mentioned in line 1. It is suggested that in line 4, “a” be replaced with --said--.

In claim 34: the recitation “essentially” in line 3 renders the claim indefinite. It is not clear what is encompassed by the term. The recitation makes the metes and bounds of the claim unclear.

In claim 38: the recitation “on average, deriving at least 50%” in line 2 renders the claim indefinite. It is not clear what is being referred to by this recitation. The metes and bounds of the claim are not clear.

In claim 39: the recitation “A 34G13 maize plant selected from the population of 34G13 progeny maize plants” renders the claim indefinite. The claim is drawn to plant 34G13, yet can comprise less than 100% of the alleles of 34G13.

In claim 40: the recitation “further comprising applying double haploid methods” renders the claim indefinite. The recitation broadens the scope of parent claim 37, which only involves crosses and does not encompass any double haploid method. It is also not clear what double haploid method is being referred to.

7. Claims 11-19, and 24-32 remain and claims 9, 10, 22, 23, 34-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 29 July 2002 under item 6. Applicant

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traverses the rejection in the paper received 29 October 2002. Applicant's arguments have been fully considered but were not found fully persuasive.

Applicants argue that seed of plant 34G13 has been deposited with the ATCC, and the claims amended to recite the ATCC accession number, and that therefore the written description requirement is met (paragraph bridging pages 12-13). However, the rejected claims are not directed towards the deposited seed or the plant that is produced from it. The deposit of seed of plant 34G13 does not provide a description of the plants that are encompassed by the rejected claims, which have not been deposited.

Applicant argues that the claims have been amended by adding the threshold, having 50% of the ancestral alleles, that limits the variation permitted among the genus, as well as an assayable function, capable of expressing a combination of at least two traits of 34G13.

Applicant argues that in plants, identifying characteristics are those detectable in the phenotype, which is manifested through gene expression, and that claims to a particular species of invention are adequately described if the disclosure of relevant identifying characteristics is present in the application. Applicants argue that one of ordinary skill is reasonably apprised in knowing that a plant crossed with 34G13 will result in a plant having half the genetic contribution of 34G13, and that a further limitation set is that the plants must be capable of expressing a combination of at least two phenotypic characteristics of 34G13 (response, paragraph bridging pages 13-14).

However, the specification does not provide a description of the alleles of 34G13, nor does it describe the functions that are associated with each of the alleles of 34G13. The specification does not describe the alleles that govern the expression of any of the traits listed in the claims.

As the alleles of 34G13 are not described, neither are the alleles of its descendents. Further, the

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new claims encompass plants that can express any traits, none of which are described.

Furtherstill, no description of any trait is provided concerning the other parents of the claimed plants. 50% of the alleles of the claimed plants will also be inherited from the other parent, for which no description is provided.

Applicant also argues that the specification supplies an extensive definition and description of “transgene” and transgenes of interest. Applicant argues that the trivial modification introduced by the transgenes to 34G13 are clearly supported and described in the present application (response, page 14, 1st full paragraph). However, as written, the claims encompass any and all transgenes, even those that have yet to be isolated and for which descriptions are unknown. Further, the effect that a transgene can have on its host plant depends on the function of its encoded product, among other considerations, and the modification cannot simply be described as “trivial.” A transgene that is a transcription factor, for example, could effect the expression of numerous genes and phenotypes. It is suggested that claims 12 and 25 be amended by listing the types of transgenes that may be introduced, provided that the specification or the prior art indicates that the gene has been isolated, for example genes that confer resistance to a plant virus.

Applicants also argue that the claims are definite (response, page 15, 1st paragraph). However, definiteness of the claims is not the issue of this rejection.

Further, the specification does not describe any traits of any inbred plants or any progeny plants produced from 34G13, nor does it mention any double haploid method. While plants produced by self or sib pollinating 34G13 would inherit all of their alleles from 34G13, the

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morphological and physiological characteristics of the progeny plants would be different from those of 34G13, as the genotype of the progeny would not be the same as that of hybrid 34G13.

8. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 29 July 2002 under item 7 for claims 1-32. Applicant traverses the rejection in the paper filed 29 October 2002. Applicant's arguments have been fully considered and found persuasive for claims 1-32. However, Applicant's arguments were not persuasive for new claim 33.

The claim is drawn towards a method of making a hybrid plant designated 34G13 comprising crossing inbred maize plant GE486259 and GE515721.

Applicant has amended the claims and the specification to recite the ATCC accession number under which seed 34G13 has been deposited. The rejection is withdrawn from claims 1-32.

Claim 33 recites the deposit numbers for two inbred maize plants, and page 7 of the specification indicates that these lines have been deposited with the ATCC. However, the terms of this deposit are not known. If the deposit of these seeds was made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the deposit was made under the terms of the Budapest Treaty and that the seeds will irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit

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requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

9. Claims 1-5, 7, and 20 are allowed. Claims 6, 8-19, and 21-40 are rejected.


Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy

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Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 6, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER